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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/779,339	02/13/2004	Christine Bernegger-Egli	A33847-PCT-USA-I 071800.0	9603
21003	7590	06/13/2006	EXAMINER	
BAKER & BOTTS 30 ROCKEFELLER PLAZA 44TH FLOOR NEW YORK, NY 10112			HANLEY, SUSAN MARIE	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 06/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/779,339

Applicant(s)

BERNEGGER-EGLI ET AL.

Examiner

Susan Hanley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10 and 11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10 and 11 is/are rejected.
- 7) ☒ Claim(s) 10 and 11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/743,391.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/13/04</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 10 and 11 are presented for examination.

Priority

It is noted that this application appears to claim subject matter disclosed in prior Application No. 09/743,391, now U.S. 6,780,634, filed 7/8/99. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and

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the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Specification

The title and the abstract of the disclosure are objected to because they do not reflect the nature of the instant invention. Correction is required. See MPEP § 608.01(b).

Claim Objections

Claims 10 and 11 are objected to because of the following informalities: A claim should be a single sentence. The MPEP states in 608.01(m) [R-3]: Form of Claims:

While there is no set statutory form for claims, the present Office practice is to insist that each claim must be the object of a sentence starting with "I (or we) claim," "The invention claimed is" (or the equivalent). If, at the time of allowance, the quoted terminology is not present, it is inserted by the Office of Patent Publication. Each claim begins with a capital letter and ends with a period. Periods may not be used elsewhere in the claims except for abbreviations. See *Fressola v. Manbeck*, 36 USPQ2d 1211 (D.D.C. 1995).

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10 and 11 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Monecke et al. ("Monecke" published in the Web: 12/11/98) in light of Csuk et al (1995; "Csuk").

Monecke discloses the racemic mixtures of the alkyl esters of (1 RS, 4 SR)- cis-4-acetamido-cyclopent-2-ene carboxylate. The esters are methyl, ethyl, 1-propyl, 1-butyl, 1-hexyl and 1-octanyl (Figure 1). The disclosure of the racemic mixtures meets the limitations of instant claims 10 and 11 because the language of the claim, or lack thereof, is considered to be open. Thus, mixture containing the claimed esters meet the claim limitations. Monecke discloses that the racemates have been previously resolved into the (-) and (+) isomers by Csuk (1995) (see the next rejection) by reacting the racemates with an enantioselective lipases. Looking to Csuk (1995) for the absolute configuration of the (-) and (+) isomers, Csuk (1995), the (+) isomer corresponds to the (1 S, 4 R) absolute configuration (based on the correlation of the specific rotation and the absolute configurations of the compounds on p. 5790-1).

The disclosure by Csuk (1995) is a supporting reference and properly used in a rejection under of U.S.C. 102 since it describes the correlation between the specific rotations and the absolute configuration of the (1 RS, 4 SR)- cis-4-acetamido-cyclopent-2-ene carboxylates MPEP 2131.01.

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Claims 10 and 11 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Csuk et al (1995; "Csuk").

Csuk discloses that racemic mixtures of the (1 RS, 4 SR)-4-acetamido-cyclo-2-ene carboxylate ester were resolved by enzymatic hydrolysis by lipases from various microbial strains. The esters included methyl, ethyl, n-butyl and n-hexyl. The racemic butyl ester was reacted with PLE or lipase P to afford the (+) and (-) butyl esters (p. 5791, Table I). In accordance with the compounds on p. 5790-1, the (+) isomer corresponds to the (1 S, 4 R) absolute configuration. The racemic hexyl ester was also subjected to hydrolysis by a number of lipases to afford the purified (+) and (-) enantiomers (p. 5792, first paragraph). The ethyl ester racemate was not resolved by any of the enzymes (p. 5791, lines 3-4). However the disclosure of the racemic mixture meets the limitation of the ethyl ester of instant claim 11 because the language of the claim, or lack thereof, is considered to be open. Thus, mixture containing the claimed esters meet the claim limitations. The disclosure of the resolved (1 S, 4 R)- butyl and hexyl esters meets the limitation of instant claim 10 wherein the ester is C₂₋₁₀ alkyl.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the

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examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Csuk et al. (1995; "Csuk").

The disclosure by Csuk 1995 is discussed *supra*. Briefly, Csuk teaches the resolution of (1 RS, 4 SR)-4-acetamido-cyclo-2-ene carboxylate ester were resolved by enzymatic hydrolysis by lipases from various microbial strains. The esters were methyl, ethyl, butyl and hexyl. Butyl and Hexyl esters were successfully resolved.

Csuk 1995 does not teach that the propyl ester racemate was subjected to enantioselective enzymatic hydrolysis to obtain the (1 S,4 R) isomer.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to resolve the propyl ester racemate. The ordinary artisan would have been motivated to do so because the propyl ester falls within the series of ethyl, butyl and hexyl and it would have been desirable to optimize the size of the alkyl group to effect the success of the enantioselective reaction. The ordinary artisan would have known from Csuk that the purpose of Csuk was to optimize enantioselective hydrolysis. This is evident in Csuk by the testing of numerous lipases as well as several in a series of alkyl esters. The genus of alkyl esters employed by Csuk is small and the propyl ester is easily envisaged, especially since it falls within the series of alkyl esters that were tested. Thus, the ordinary artisan would have realized that it would have been advantageous to test the propyl ester racemate with the various lipases to optimize the reaction variables of the size of the alkyl ester group in combination with the best lipase to bring about the desired enantioselectivity. The ordinary artisan would have had a reasonable expectation that the reaction of the propyl ester racemate and the various lipases could be carried out and analyzed because the reaction conditions and analysis would essentially be the same as for the other alkyl esters.

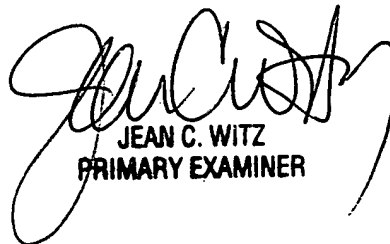
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Hanley whose telephone number is 571-272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Susan Hanley
Patent Examiner
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JEAN C. WITZ
PRIMARY EXAMINER